Appendix 1

TO: Mr. C. H. Goldsmith November 15, 1968

FROM: H. Wakeham

SUBJECT: Need for Biological Testing and Research by Philip Morris Research and Development

Most Philip Morris products, both tobacco and non-tobacco, are directly related to the health field. Consumer health is a focal point of interest and concern to the general public and to the government. This trend is a natural one which attends an affluent society. There is every indication that technically, sociologically, and economically we will have to deal with an ever increasing concern for the health aspects of our products. Consequently, if R&D is to fulfill its technical responsibilities, we will require significantly increased capabilities to investigate the health implications not only in tobacco but also in gum, confections, and the medical products fields.

The issue of health in the tobacco field has advanced rapidly in the last year to the point where the opponents of smoking are effectively playing on the fears of the public. Their influence is based on a well organized campaign that could culminate in the restriction of television and radio advertising. We have seen institution by the government of comparative brand testing for TPM and nicotine. It is likely that this testing program may be extended to include other chemicals. We also see and anticipate as realistic and as a next step the institution of a biological testing program on competitive brands for carcinogenic potentials and possibly publication of these figures. The techniques for doing such testing are available, irrespective of the validity of the findings which at this point are technically judgmental and questionable. These techniques have been established by Drs. Bock, Boutwell, Saffiotti, Kensler, Wynder, and others and are in the literature. We have also received during the past year an inquiry from the Department of Agriculture requesting our comments or recommendations for methodology in testing tobacco smoke for biological activity.

While we have maintained to the best of our ability a technical intelligence system designed to be alert to any studies associated with tobacco smoke, these programs are closely guarded secrets and our knowledge usually comes after the fact in the form of publications. More importantly it is our experience that Research Study funds provided by the Tobacco Industry through the offices of AMA as well as public funds are applied to studies oriented to seeking out and highlighting the negatives associated with tobacco smoke.

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In this situation we face a real need to obtain our own facts and data in biological systems, in order to avoid being surprised by information from outside sources and in order to interpret and understand the results of such studies. If comparative brand biological testing by the government is ever realized, we need to be in a position of technical competence in this area similar to that we had developed in the Analytical field. In order to achieve this competence we must have a facility of our own in which to develop, test, and subject our own products and other brands to biological studies so that we may have knowledge and competence in this field. It is not unreasonable to assume that with the introduction of biological testing and publishing of data by the government, all tobacco companies will find it necessary defensively to embark on their own testing programs either in-house or at available consulting biological laboratories. When this situation arises, inadequate preparedness on our part may put us in an extremely difficult position. In the first place, since biological testing requires extended time not only to develop competence but to conduct the actual test, we may be too late to counteract competition or other outside forces. Secondly, since outside biological testing facilities are limited in number and since many are supported in great part by government contracts they may either already have our competitors as clients or be reluctant to take on studies for fear of offending their government sponsors. Politically and socially stigmatized in such a situation our own data from our own facilities might constitute our only source of legal/technical defense.

We have reason to believe that while this proposal to carry out biological research and testing may seem a radical departure from previous policy and practice, we are in fact only advocating that which our competitors are also doing. The American Tobacco Company in its new facilities at Bermuda Hundred has included several animal rooms, one for dogs, and one for smaller animals, as well as an autopsy room. Further, the biomedical work supported by American Tobacco at the Medical College of Virginia under the supervision of Dr. Arthur Burke (M.D.) was relocated under conditions of extreme secrecy during this past summer from the college to their new research facilities at Bermuda Hundred. Some studies are still being continued at the Medical College but the major portion is now within their own house.

R. J. Reynolds has expanded its research facilities at Whitaker Park, Winston-Salem. Their new Product Development Laboratory contains in addition to their tobacco research program expanded pharmacological and toxicological laboratories presently devoted to research and development in the food field. However, these disciplines are equally applicable to biological studies in the tobacco field and represent a reservoir of biological capability ready at a moment's notice to be applied to the pharmacology and toxicity of smoke if needed. The recent demonstration by Reynolds of their

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ability to develop on short notice a highly sophisticated smoke inhalation machine confirms this impression. They specifically admitted six months of actual experience with animals with a prototype machine.

We have recently obtained a very close insight into the extensive program which Liggett & Myers has carried on for the past 15 years with the Life Sciences Division of Arthur D. Little, Incorporated. In this work they have touched almost every facet of the smoking and health area, including chemical analyses, epidemiological studies, and bioassay tests. Clearly their background and their biological commitment at Arthur D. Little is much more extensive than ours, and provides them with a strong reservoir of life science capability which they can tap as the occasion demands.

Lorillard Corporation has to the best of our knowledge limited its activities to small contracts at the Illinois Institute of Technology Research Institute and the Karolinska Institutet in Stockholm. So far as we know, they have no in-house program.

Brown and Williamson is in the unique position as a part of the British-American complex to be supported by the extensive biological facilities of the parent company in England and Germany.

While we have emphasized our need for biological capabilities in support of our tobacco interest we have an equal if not greater need for biological capabilities to support the future of our diversified interests. Our present plans and studies in the gum field encompass products designed to prevent dental caries and reduce calculus from teeth. We are also aiming at other Quasi-pharmaceutical gums containing active therapeutic ingredients. In all instances we are faced with establishing the toxicological safety of the various additives or ingredients in our products. Both marketing needs and advancing technology demand that products of the immediate and later future must possess demonstrable efficacy.

Our interest in the food field presently focused on confections requires the biological capability to show the safety of any food additives or ingredients required, and to support efficacy and safety of anti-caries ingredients in confections as well as the efficacy of protein containing foods in which we have a long range interest. Again this is a line of activity already being carried out by Reynolds and American who are also in the food business, as well as by American Chicle in connection with their gum products.

Biological capability to support the development of products in the field of medical needs is obvious. Essential to the development and introduction

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of any product are the biological studies proving safety of the product as well as efficacy to satisfy the Food and Drug Administration requirements. The very nature of our hospital products requires technical competence in the field of microbiology relative to the sterility of our products. Finally strong competence in the biological testing field is extremely valuable to support our marketing and product image in the hospital products field. Benefits such as these, although real, cannot be measured in terms of sales dollars.

In summary, our needs for expertise in life science areas are increasing rapidly, not only because of greater emphasis on the smoking and health controversy, but also because of our involvement in health sensitive non-tobacco product lines. Unfortunately these needs cannot be ignored. We must know more about our products than anyone else so that we are not surprised when our competitors or our antagonists publish information about our products. We must know how our products perform in conventional tests regardless of whether or not we believe the tests to be significant. In short, we must find a way to meet our needs for biological testing and research in the most effective manner consistent with the broad interests of our business.

H Wakelin

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